



HUMAN SUBJECTS RESEARCH APPLICATION FORM
To be completed by all investigators using human subjects in research

Date: _____

Project Title: _____

Principal Investigator(s) _____

Name

signature

Name

signature

Name

signature

If student(s), faculty sponsor:) _____

Name

signature

(if class project, faculty member may append class roster)

Department _____ Phone _____

Funding sources, if any: _____

Briefly describe the nature of the research and the part of human subjects in it.

This research falls into category _____ as described on page two of this form.

Approved: _____

Signature

Date

Name and Title: _____

I. Please indicate which of the following categories your research fits into.

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. Research involving the use of education tests such as cognitive, diagnostic, aptitude and achievement tests, in which either of the following conditions exists:

information obtained is recorded in such a manner that human subjects can not be identified directly or through identifiers linked to the subjects;
disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

C. Research involving survey or interview procedures, or observation of public behavior in which either of the following conditions exists:

information obtained is recorded in such a manner that human subjects can not be identified directly or through identifiers linked to the subjects;
disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

D. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, which sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

E. None of the above.

If you have indicated category A, B, C, or D, your research is exempt from any further review and you should stop here and submit this form to your CRB. You then may proceed with your research.

If your research involves human subjects and does not fit into category A, B, C, or D, but rather you checked E, then you must also complete Section II.

If your actual research changes from that described above in a way which puts human subjects at risk, resubmit the Application Form to the appropriate URB or CRB Chairperson before proceeding further. If the research as conducted is substantially the same as described above, no action need be taken.

II. Complete this section if your research does not fit categories A, B, C, or D above.

1. The risk to human subjects of this research is minimal.

Yes

No

Briefly describe the risk, regardless of whether you answered "yes" or "no".

If you answered "yes," skip to question three.

2. In relation to the anticipated benefits to the subject and the importance of the knowledge that is expected to result from this research, the risk to the subject is reasonable.

Yes

No

If you answered yes to this question, please attach a research proposal describing your research plan.

3. Will informed consent be sought from each prospective subject or the subject's legally authorized guardian in accordance with the code of ethics for conducting research within your disciplines?

Yes

No

If you answered yes to this question, attach the informed consent form you propose to use. (Adapt the template consent form below.)

If you answer no, you may request a waiver of consent if the risk to the human subjects of your research is minimal and the research could not practically be conducted with informed consent. To request such a waiver, attach to this form an explanation of why research could not otherwise be done if informed consent were required. (Documentation must be maintained by the researcher for no less than three years.)

4. This research will involve vulnerable populations such as children, people with mental disabilities, etc.

Yes

No

If you answered yes to question 4, please attach an explanation of what safeguards you plan to implement to protect these populations.

5. What provision have you made to monitor data collection to ensure the safety of others?

6. Are there adequate safeguards to protect the anonymity and confidentiality of your subjects?

Yes

No

If you answered yes to question 6, please attach an explanation of what safeguards you plan to implement to protect these populations.

III. Monitoring Process:

If the research as conducted remains substantially the same as approved, then you need only sign the Monitoring Form at the completion of the research. If your actual research changes from that approved in a way which increases the risk to human subjects, see the guidelines for exempt v. non-exempt research on the attached monitoring form.

Human Subjects Research Disclosure Form

Project Title:

Principal Investigators:

Description:

Purpose and Procedures:

Compensation:

Risks/Benefits to the Participant:

Confidentiality: All documents and information pertaining to this research study will be kept confidential. I understand that data generated by the study may be reviewed by Rider University's Institutional Review Board, which is the committee responsible for ensuring my welfare and rights as a research participant, to assure proper conduct of the study and compliance with university regulations.

Participant's Right to Withdraw from the Study: At any time you may elect to withdraw from participation in this research study. If you choose to withdraw from this study please contact the investigator and your survey will be destroyed.

Other: Rider University will not provide special services, free care, or compensation for any injuries resulting from this research.

Questions: If you have further questions about this study, contact the Principle Investigator. If you have any questions about the rights of research participants, call Dr. James Ottavio Castagnera, Chair of Rider University's Institutional Review Board, at 609-86-5035.

Voluntary Consent: I understand that my participation in this study is entirely voluntary, and that refusal to participate will involve no penalty or loss to me. I am free to withdraw or refuse consent, or to discontinue my participation in this study at any time without penalty or consequence. I voluntarily give my consent to participate in this research study. I understand that I will be given a copy of this consent form.

Signatures:

Participant's Name (Print)

Participant's Signature / Date

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form has had the study explained by me and has been given an opportunity to ask any questions regarding the nature, risks, and benefits of participation in this research study.

Principal Investigator's Name (Print)

Principal Investigator's Signature/Date

Monitoring Form

Exempt Research

If your actual research changes from that approved in a way which puts human subjects at risk, please resubmit the Application Form to the appropriate IRB Chairperson or Member before proceeding further. If the research as conducted is substantially the same as approved, no action need be taken.

Nonexempt Research

If your actual research changes from that approved in a way which increases the risk to human subjects, please resubmit the Application Form with the changes noted before proceeding further. If the research as conducted is substantially the same as approved, then this researcher need only sign the Monitoring Form at the completion of the research.

I hereby certify that the research conducted did not differ from that proposed in a way that increased the risk to human subjects.

Name _____

Date _____

Title of
Study: _____
